

**REMARKS**

Claims 1-24 are pending. Claims 1, 3-5, 8, 11, 15, 16, 18, and 20-24 are rejected. Claims 2, 6, 7, 9, 10, 12-14, 17 and 19 are indicated to contain allowable subject matter. By this Amendment, claim 22 is amended. Reconsideration is respectfully requested in view of the claim amendment and the following remarks.

**Claim Rejections Based on § 103(a)**

The Office Action rejects claims 1, 3-5, 8, 11, 15, 16, 18, and 20-24 under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 6,645,140 to Brommersma in view of U.S. Patent No 6,599,237 to Singh. The rejection is respectfully traversed.

U.S. Patent No. 6,645,140, titled "Continuously Rinsing Double-Sheath Endoscope" (hereafter "Brommersma"), describes a continuously rinsing double-sheath endoscope that includes an inner sheath and an outer sheath. The inner sheath includes a feed duct and receives an optics. The outer sheath surrounds the inner sheath and cooperates with the inner sheath to subtend a return flow duct. The outer sheath is fitted at its distal end zone with at least one aperture to establish fluid communication between the return duct and the ambience of the outer sheath. The cross-sectional centers of the inner and outer sheaths are offset to improve flow through the return duct.

U.S. Patent 6,599,237, titled "Instrument and Method for Facilitating Endoscopic Examination and Surgical Procedures" (hereafter "Singh"), describes an endoscope that includes an inflatable balloon near the distal end. The endoscope also includes a peripheral duct for introducing anesthetic or lubricant during insertion through an opening near the distal end.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be some expectation of success. Third, the prior art references must disclose or suggest all of the claimed features. MPEP 2143. Applicants respectfully submit that these criteria have not been met.

In the Office Action, elements 17b (return duct or gap) and 19b (apertures) of Brommersma are relied upon to show that fluid emanating therefrom would be distributed in an even fashion throughout the body cavity being examined. However, fluid does not emanate from the return duct and apertures of Brommersma. The apertures situated on the outer sheath shown

in Brommersma function only as a return path for fluid in the body cavity. Singh discloses an endoscope that includes a passage and single opening to introduce an anesthetic, lubricant or other fluid into the body cavity. The inflatable balloon disclosed in Singh is not in fluid connection with the passage and opening for the anesthetic, lubricant or other fluid. Rather, the retention balloon prevents fluid expelled through the opening from seeping away from area to be medicated (*see* Singh, col. 5, lines 3-21).

In contrast, claim 1 of the present invention provides, in part, “an endoscope comprising an operating unit and a flexible shaft that includes at least one lumen; and an *anesthetic collar* comprising an annulus, wherein said anesthetic collar is adapted for placement on said flexible shaft so as to permit free transfer of a fluid through said at least one lumen of said flexible shaft to said annulus and wherein said annulus comprises an enclosed chamber having a hollow core and one or more *expulsion* pore to permit fluid flow into the gastrointestinal tract of a patient.” Neither of the cited references disclose an annulus with expulsion pores. As noted above, the elements 16b relied upon in Brommersma are not expulsion pores. Singh does not supply this deficiency by disclosing a passage leading directly to a single opening without a collar. Furthermore, neither of the cited references disclose an anesthetic collar adapted for placement on a flexible shaft so as to permit free transfer of a fluid through at least one lumen of said flexible shaft to said annulus. Brommersma, for example, does not disclose a device with fluid communication between the inner and out sheaths. Singh does not disclose a collar that includes one or more expulsion pore.

Thus, neither Brommersma nor Singh individually or in combination teach or suggest the invention recited in claim 1. In particular, the combination fails to teach or suggest use of an anesthetic collar comprising an annulus with one or more expulsion pore, as recited in claim 1. In addition, neither Brommersma nor Singh provide the requisite motivation to modify and/or combine their teachings to arrive at the Applicant’s claimed invention. For example, neither the bulge 20b of Brommersma nor the balloon 24 of Singh are used to expel fluid.

Claims 3-5 and 8 depend from independent claim 1. Thus, it is respectfully submitted that dependent claims 3-5 and 8 are distinguishable over the applied references for at least the reasons described above. Therefore, withdrawal of the rejection of claims 1, 3-5 and 8 is respectfully requested.

Claim 11 of the present invention provides, “An anesthetic collar for providing gastrointestinal pain management during an endoscopic procedure, comprising: an **annulus** including an enclosed chamber having a hollow core and **discharge means** so as to permit discharge of fluid from the enclosed chamber through the annulus; and means for securing said annulus to a flexible shaft of an endoscope.” Similar to claim 1, neither of the cited references disclose an annulus including an enclosed chamber having a hollow core and discharge means. As noted above, the elements relied upon in Brommersma do not discharge fluid. Singh does not supply this deficiency by disclosing a passage leading directly to a single opening without an annulus. Furthermore, neither of the cited references disclose an anesthetic collar including discharge means so as to permit discharge of fluid from the enclosed chamber through the annulus. Brommersma, for example, does not disclose a device with fluid communication between the inner and out sheaths. Singh does not supply this deficiency because there is no collar or other enclosed chamber in fluid communication with the passage used to expel fluid. Thus, neither Brommersma nor Singh individually or in combination teach or suggest the invention recited in claim 11.

Claims 12-14 depend from independent claim 11. Thus, it is respectfully submitted that dependent claims 12-14 are distinguishable over the applied references for at least the reasons described above. Therefore, withdrawal of the rejection of claims 11-14 is respectfully requested.

Claim 16 of the present invention provides, in part, “a lumen extending from a fluid delivery mechanism, wherein said lumen is capable of being inserted through an internal tubular cavity along a flexible shaft of an endoscope and **passing beyond the distal end of said shaft**; and a head comprising a **plurality of expulsion pores**, wherein said head is connected to the distal end of said lumen so as to allow free flow of fluid from said lumen through said expulsion pores so as to facilitate comprehensive dispersion of said fluids into a patient’s gastrointestinal tract.” In addition to the differences noted above, neither of the cited references disclose a lumen passing beyond the distal end of said shaft. Thus, neither Brommersma nor Singh individually or in combination teach or suggest the invention recited in claim 16.

Claim 18 depends from independent claim 16. Thus, it is respectfully submitted that dependent claim 18 is distinguishable over the applied references for at least the reasons

described above. Therefore, withdrawal of the rejection of claims 16 and 18 is respectfully requested.

Claim 20 of the present invention provides, in part, “a fluid lumen extending along the length of said flexible shaft so as to permit free transfer of a fluid; and ***one or more outlet lumens*** connected to said fluid lumen and arranged such that said fluid passing through said fluid lumen is distributed in an even fashion throughout the path of travel of said flexible shaft.” In addition to the differences noted above, neither of the cited references disclose one or more outlet lumens. Presuming, *arguendo*, that the return duct 17b of Brommersma meets the limitations of the claimed fluid lumen, no other element exists to qualify as the claimed outlet lumens. Singh does not supply this deficiency, since only a single fluid lumen is disclosed. Thus, neither Brommersma nor Singh individually or in combination teach or suggest the invention recited in claim 20.

Claim 21 depends from independent claim 16. Thus, it is respectfully submitted that dependent claim 21 is distinguishable over the applied references for at least the reasons described above. Therefore, withdrawal of the rejection of claims 20 and 21 is respectfully requested.

As amended, claim 22 of the present invention provides, in part, “providing a fluid delivery means, wherein the fluid delivery means may be one of an anesthetic collar, an insertion member, and a fluid lumen and outlet lumens integrated into said flexible shaft.” As discussed above with respect to claims 11, 16 and 20, neither Brommersma nor Singh individually or in combination teach or suggest fluid delivery means of (1) an anesthetic collar, (2) an insertion member, or (3) a fluid lumen and outlet lumens integrated into said flexible shaft. Thus, neither Brommersma nor Singh individually or in combination teach or suggest the invention recited in claim 22.

Claims 23 and 24 depend from independent claim 22. Thus, it is respectfully submitted that dependent claims 23 and 24 are distinguishable over the applied references for at least the reasons described above. Therefore, withdrawal of the rejection of claims 22-24 is respectfully requested.

Application No. 10/724,871  
Amendment dated January 25, 2004  
In reply to Office Action mailed August 13, 2004

### CONCLUSION

In view of the foregoing, Applicant submits that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that the prosecution of this case might be advanced by discussing the application with Applicant's representative, in person, or over the telephone, we would welcome the opportunity to do so.

EXCEPT for fees payable under 37 CFR §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit, any overpayment to deposit account No. 50-1349. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 CFR §1.136(a)(3).

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1349.

Respectfully submitted,

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